**ON-SITE ASSESSMENT STANDING COMMITTEE**
**NELAC Interim Meeting**
**December 6-8, 1995**
**Arlington, VA**

**Attending Members:**

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|---|---|---|
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**Issues:**

**Introduction**

Chairman Boozer introduced the committee members; all committee members attended except Steven Ankabrandt and Chris Given. The agenda for this session is to revise Chapter 3 section by section.

The need for representation on the committee relative to good laboratory practices (GLPs) was raised. The committee chair stated that the GLP issue was still to be addressed by the National Environmental Laboratory Accreditation Conference (NELAC) through input from the Environmental Laboratory Advisory Board (ELAB). Since this process is just beginning, the committee will not make any revisions for GLPs at this time.

It was noted that Chapter 3 is not a stand-alone chapter and any changes must be consistent with

the language of the document as a whole.

Where appropriate, recommended additions appear in *italic* and recommended deletions appear as ~~strikeouts~~.

## Chapter 3

### Section 3.1 - Introduction

In the second paragraph, the phrase "facilitate reciprocity among states" was changed to "facilitate reciprocity." In the third paragraph, there was a discussion about reporting health and safety regulations and unsafe conditions. This issue needs further clarification on two points: 1) to whom the assessor reports unsafe conditions, and 2) health and safety training needed by the assessors.

Section 3.2.1 - Training

Comments have already been received and further comments were solicited. Most of the States expressed concern regarding the cost incurred for sending assessors to training courses. Questions were raised on the number of auditors a State needs.

Section 3.2.2 - Qualifications

The committee will look into changing the language in this section to be more specific. The point was brought up that the wording of standards needs to be specific. Of concern were the phrases "laboratory operation" and "Federal, State, or third party accrediting body." The wording of the standards needs to be specific enough to prevent non-uniform interpretation of these standards and qualifications.

Section 3.2.3 Additional Qualifications

The need for a separate section on additional qualifications in conjunction with ISO standards for team leaders versus assessors was raised. Distinct qualifications for lead assessors versus other members of the team was also discussed.

Section 3.2.4 - Assessor Certification

The committee decided to address assessor certification after finalizing training requirements. One person expressed concern with "grandfathering" of assessors; specifically, whether a need for additional certification under the National Environmental Laboratory Accreditation Program (NELAP) exists when one is already a certified ISO assessor.

It was noted that the phrase "conflict of interest" was not clearly defined. For example, the case when a laboratory has a problem with a particular assessor (e.g. the assessor being a former employee of the laboratory) could be considered as a conflict of interest. In addition, the issue of

whether trainers should be assessors was raised; it was noted that Section 6 precludes this. It was suggested that more sections be added here, such as what is meant by "conflict of interest;" assessor code of conduct and assessor responsibilities. The committee agreed to look into this issue further. It was suggested that no one (even State and Federal authorities) should be excluded from being scrutinized for "conflict of interest." Assessors should sign a statement clarifying that they have no conflicts of interest.

Section 3.3.1 - Frequency

There was general discussion on how the States would react to various assessment frequencies. Some State representatives indicated that if assessments were any more frequent than every three years, they wouldn't participate in NELAC; other States indicated that if assessments were less frequent than annually, they wouldn't participate. One possible compromise is to specify full assessments every three years, with surveillance assessments annually. While surveillance assessments would save money, it was pointed out that the goal in establishing frequency should be to maintain laboratory quality, not to save money. The general concern was that quality might be sacrificed with a frequency of every three years between audits. On revisiting this issue, a satisfactory consensus was not achieved. However, a compromise of once every two years was suggested. A frequency number must be proposed for voting in the June/July meeting.

Another related issue was the realistic scope and depth of an audit in a given time frame with limited personnel resources. A recommendation was made to allow some latitude in the language so that "good" laboratories could get waivers, thus reducing the burden on assessors in order to focus on "problem" laboratories.
The wording in the statement "... complaints about quality have been received ..." needs to be clarified.

Section 3.3.2 - Follow-up Evaluations

The 45-day limit for completing and reporting follow-up assessments was discussed. It was unclear what the time limit actually is and what activities must be completed during that period. After discussion, it was decided that the committee would reword this section. It was suggested that 30 days be allocated for the first assessment report, 30 days for the response, and 45 days from the period after the response has been received before a decision on accreditation is made.

The types of information that assessors should look for during the follow-up assessment and the role of surveillance audits with respect to follow-up audits were discussed.

Section 3.3.3 - Changes in Laboratory Capabilities

There was no discussion on this issue.

Section 3.3.4 - Announced and Unannounced Visits

The wording of this section will reflect the content of Chapter 4.1.2, which is being revised by the

Accreditation Process Committee. Specifying when announced and unannounced visits are appropriate depends on that committee's revisions.

**Section 3.4. Preassessment Procedures**

Some of the material in this section has been struck because it is more appropriate for the assessor's manual -- not for standards.

Section 3.4.1 - Introduction

The committee plans to edit this section to ensure that it deals only with preassessment activities.

Section 3.4.2 - Scope of the Assessment

Discussion included the suggestion to delete the last phrase, "... or has already been accredited"; to consistently use either the singular or the plural of "assessment"; and to make the wording internally consistent.

The final wording will reflect the decision made by this committee or by the Accreditation Process Committee.

Section 3.4.2.1 - Laboratory Evaluations

It was explained that the committee suggests striking the original first sentence ("A laboratory assessment ...") to better state issues in the new first sentence ("A general laboratory assessment ..."). The word "overall" was dropped.

In the second sentence, the following change was suggested: "... ~~accurate~~ work *of known quality* ~~without major deficiencies~~."

It was suggested that the third sentence read: "The examination of ~~the~~ *systems*, processes, and procedures ..." be added to reflect ISO standards.

Section 3.4.2.2 - Records Review

During discussion of this section, it was suggested that the phrase "to obtain objective evidence" replace "to ascertain whether"; that the word "data" be changed to "collected information"; and that the phrase "proper NELAC procedures" be clarified.

Section 3.4.3 - Assessment Planning

Section 3.4.3 ("Assessment Planning") will precede Section 3.4.2 ("Scope of the Assessment").

Section 3.4.4 - Reviewing NELAP/State Information

Change the second sentence as shown: "... maintained by the NELAP ~~shall~~ *should* ..."

The committee will consider combining "c" and "d" and possibly rephrasing "NELAP/state" to "accrediting authority." The title of the section will be changed to "Information Collection and Review."

It was agreed that "f" be deleted.

The committee will globally replace "assessor team" with "assessor(s)," and "NELAP/state" with "accrediting authority."

Section 3.4.5 - Assessment Documents

The intent of the revision to this section was so that assessors need not carry all relevant documents with them to assessments; rather, the assessors can provide information to the laboratories for obtaining the documents.

It was decided to consider adoption of ISO definitions at a later time.

Section 3.4.6 - Confidential Business Information Considerations

The committee moved the last paragraph (and the last sentence) in Section 3.5.3 to Section 3.4.6 and added a statement that confidential business information (CBI) applies to all areas of a site.

After discussion about who should mark information confidential, the committee changed the text to indicate that it was each laboratory's responsibility to mark confidential material. This relieves the assessors of the burden and liability of accidentally revealing confidential material.

Section 3.5.1 - Length of Evaluation

No comments.

Section 3.5.2 - Opening Conference

The first line in the third paragraph was changed to read: "Topics that ~~must~~ *should at least be included* during the opening conference ..."

In subsections "c," "d," and "h," the word "specific" was removed.

The committee agreed to reword subsection "j" to ... ~~completion of the assessment appraisal form by~~ *provide assessment appraisal* to the responsible laboratory official."

Subsection "k" was added: "Clarify any unclear details of the assessment process."

Section 3.5.3 - Records Review

It was suggested that the title of this section be changed to "*On-Site* Records Review."

Second paragraph, first sentence: "A minimum record set that must be examined *as part of* NELAP accreditation ~~on-site~~ assessment includes; ...."

The committee will consider whether the language in this section, as well as in Section 3.4.4, is too restrictive about when assessors can review records (a distinction between preassessment and on-site records should be made).

A subsection "r" (records of an annual management review of the design implementation of the laboratory's quality systems) will be added to this section. This specification is already included in Section 5.5.3; however, it will be included here after review by the Quality Systems Committee.

Section 3.5.4 - Staff Interviews

In the second paragraph, the committee decided to make the following change: "The assessment team members shall have the authority to conduct interviews with any/all staff ~~and, if necessary, conduct private interviews.~~"

Discussion of the assessor's responsibility in reporting violations of the law as stated in the fifth paragraph indicated that the word "violation" may be too strong; assessors are not lawyers and cannot be accountable for all aspects of the law (beyond NELAC standards). The committee will look into moving this entire paragraph to Section 3.6.2. The wording will remain unchanged.

Section 3.5.5 - Closing Conference

No changes; no discussion.

Section 3.5.6 - Follow-up Procedures

The second paragraph was changed as follows: "After reviewing the assessors reports and ~~any~~ corrective action ~~noted~~ by the laboratory, the accrediting authority will make the *determination of the accreditation status of a laboratory* ~~decision to pass, fail, or provide interim accreditation for a laboratory.~~"

There was much discussion about the "30-day" and "45-day" followup. Many members felt that the time frame needed to be lengthened and that the wording needed to clarify what would be included in the reports due at a certain date, as well as the response dates. The committee will work with the Accreditation Process Committee to resolve these issues.

Section 3.6 - Criteria for Assessment

No comments.

Section 3.6.1 - Assessor's Manual

The committee will decide later who will develop the manual and where the development funds will come from.

Section 3.6.2 - Assessor's Role

The terms “specific” and “opening conferences” were discussed; the committee will decide this issue later.

Section 3.6.3 - Checklists

The committee will decide later whether there will be one NELAC-approved checklist, a “minimum” NELAC-approved checklist, or whether States will have their own checklists.

Section 3.6.4 - Evaluation Criteria

This section will be deleted to avoid potential overlap or conflict with Chapter 5 being developed by the Quality Systems Committee for incorporation into the NELAC assessors' manual.

The committee moved Section 3.6.4 into Section 3.6.1. (Section 3.6.4 will refer to the appropriate Quality Systems chapter, so that there will not be duplication or contradiction of effort.)

Section 3.6.4.1 - Facility Assessment

The committee decided to change the wording from “tour” to “assessment” in certain areas as marked in the text. This section was subsequently deleted.

Section 3.7.1 - Checklist

The committee replaced the term “NELAP/state” with “accrediting authority” so the new wording now reads “... kept by the *accrediting authority* on ...”.

Section 3.7.2 - Report Format

The committee decided to move the last paragraph in front of the list of report contents. It was suggested that a section on corrective actions to be taken be added between sections “g” and “h.”

Discussion touched on specifying a place in the report stating the amount of time for the laboratory to respond. The coverage and placement of the deficiencies in the report, as well as a listing of past deficiencies, the following were discussed. The committee will revisit the wording later.

Section 3.7.3 - Distribution

The committee made the following changes: "The accrediting authority ~~should~~ *shall* be recognized as having the responsibility for the ~~content~~ *distribution* of the evaluation reports. The assessment team leader ~~should~~ *shall* compile, edit, and submit the final report to the accrediting authority. ~~The team leader must assure that the results within the final report conform to established criteria for the evaluated parameters~~."

Section 3.7.4 - Report Deadline

The committee made the following changes: "No ~~longer~~ *more* than thirty (30) days ~~should~~ ~~may~~ *shall* elapse from the *completion of the assessment* ~~last day of an on-site evaluation~~ until the report is ~~submitted to the~~ completed by the accrediting authority and copies transmitted to the laboratory and the National Accreditation Database ~~for review and final decision~~. An exception to this deadline may be necessary in those circumstances where an investigation or other ~~regulatory~~ action has been initiated *by the accrediting authority, in which case the laboratory would be notified*." Specification should be made regarding who (at a minimum, the laboratory director and assistant director) should be notified and when.

Section 3.7.5 - Release of the Report

No changes were made.

Section 3.7.6 - Report Storage Time

The sentence was changed to read: "Copies of all *assessment* ~~evaluation~~ reports *and laboratory responses* must be retained..."